

## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
4 August 2005 (04.08.2005)

PCT

(10) International Publication Number  
**WO 2005/071410 A1**

- (51) International Patent Classification<sup>7</sup>: G01N 33/53, 33/543, 33/551
- (21) International Application Number: PCT/US2005/000416
- (22) International Filing Date: 7 January 2005 (07.01.2005)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data: 60/481,891 13 January 2004 (13.01.2004) US
- (71) Applicant (for all designated States except US): TANOX, INC. [US/US]; 10301 Stella Link, Houston, TX 77025 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): WANG, Yajun [CN/US]; 2418 Lansing Circle, Pearland, TX 77584 (US). LIU, Meng, Yuan [CN/US]; 3234 Braesview Dr., Pearland, TX 77584 (US).
- (74) Agent: LILJESTRAND, Cheryl, A.; Tanox, Inc., 10301 Stella Link Road, Houston, TX 77025 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:  
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: DETECTING AND QUANTIFYING HOST CELL PROTEINS IN RECOMBINANT PROTEIN PRODUCTS

(57) Abstract: A single-step immunoassay method, kit, and reagents for detecting and quantifying contaminant host cell proteins in a recombinant protein sample are described. The method includes the step of adding to immobilized medium comprising a capture reagent including anti-host cell protein antibodies, both the recombinant protein sample and a detection reagent comprising anti-host cell protein antibodies and a detectable moiety. The recombinant protein sample and two reagents are added simultaneously. This single-step format provides greater interaction between the capture antibody, the contaminant host cell proteins that may be present in the recombinant protein sample, and the detection antibody. By providing the opportunity for both antibodies and HCPs to interact at the same time, the one step format allows the formation of the "capture antibody-HCP-detection antibody" complex with all possible HCPs present. Thus, the HCP assay sensitivity is significantly improved, and the possibility of a false negative is significantly reduced. In addition, the one step format shortens the assay turnaround time and provides a convenient tool for measuring the HCP in the product during the course of the entire purification procedure. Quality control of the process is increased and the protein purification efficiency during process development can be measured.



WO 2005/071410 A1